

REMARKS

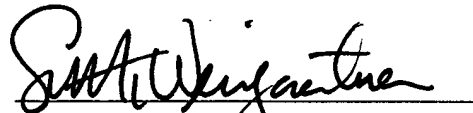
Applicants have amended the application to cancel claims 24, 27-30, 32-34 and 36 in order to focus the issues for appeal. With respect to the claims that remain pending, Applicants have amended claims 22, 25, 26 and 35 in order to address matters of a purely typographical nature.

Applicants submit that none of the claim amendments is made in acquiescence of any objection or rejection relating to patentability. Rather, certain claims were canceled and others amended purely for typographical reasons to advance the application and to facilitate appeal of the final rejection. Applicants reserve the right to file one or more continuation applications to establish the patentability of claimable subject matter that may have been removed by the claim amendments.

Applicants respectfully submit that, particularly in view of the reasoning provided in the accompanying Appeal Brief, the pending claims are directed to allowable subject matter and their allowance is accordingly respectfully urged.

Dated: May 10, 2004

Respectfully submitted,



Scott T. Weingaertner
Reg. No. 37,756
Attorney for Applicants

Customer No. 007470
White & Case LLP
Direct Line: (212) 819-8404

APPENDIX OF CLAIMS

22. (Previously presented) A method for treating diabetes mellitus in a patient comprising the steps of:

- a. supplying a predetermined amount of dry insulin powder to an inhalation device;
- b. releasing a pressurized gas over the predetermined amount of dry insulin powder to create an aerosolized suspension comprising powder suspended in air, wherein the aerosolized suspension contains an amount of insulin that is 2-10 times higher than the amount needed to be absorbed in the ~~blood-stream~~ bloodstream of the patient; and
- c. inhaling the aerosolized suspension at a flow rate and volume sufficient to allow the patient to absorb in the bloodstream a controlled dose of insulin that comprises between 1-50 units of insulin.

23. The method of claim 22, wherein steps a-c may be repeated periodically as needed to treat the patient and wherein the amount of insulin supplied to the bloodstream in step c remains relatively constant for each repetition of steps a-c.

24. (canceled)

25. (Amended) A repeatable method of regulating blood glucose levels in a human patient, the method comprising the steps of:

- a. supplying a fixed quantity of dry insulin powder to a portion of a hand held inhalation delivery device;
- b. propelling a gas over the fixed quantity of dry powder to produce, in a repeatable manner, an aerosolized suspension of insulin, the aerosolized suspension containing more insulin

~~then than~~ is required in the ~~blood-stream~~ bloodstream of the patient to achieve a satisfactory blood glucose level; and

c. flowing at least a portion of the aerosolized suspension through a mouth piece on the device and into the lungs of the patient in a manner sufficient to cause the patient to absorb in the ~~patients~~ patient's bloodstream a sufficient, controlled quantity of insulin to achieve acceptable blood glucose level following treatment.

26. (Amended) The method of claim 25, wherein steps a-c may be repeated periodically as needed to treat the patient and wherein the amount of insulin supplied to the ~~blood-stream~~ bloodstream in step c remains relatively constant for each repetition of steps a-c.

27. (canceled)

28. (canceled)

29. (canceled)

30. (canceled)

31. A repeatable method of lowering a patient's serum glucose level to acceptable value, the method comprising the steps of:

- a. supplying a predetermined amount of dry insulin powder to a medical device;
- b. releasing a compressed gas over the dry insulin powder to form a suspension comprised of dry insulin powder and air; and
- c. inhaling at least a portion of the suspension at a flow rate and volume sufficient to deposit a sufficient, controlled quantity of insulin in the patient's lungs so that the patient absorbs

into the blood between 1 and 50 units of insulin, thereby lowering the patient's blood glucose level to an acceptable value between 50 mg/dl and 300mg/dl.

32. (Canceled)

33. (Canceled)

34. (Canceled)

35. (Amended) A method of administering insulin to a diabetic patient to control serum glucose levels via a hand held inhalation device, the method comprising the steps of:

- a. supplying a predetermined quantity of insulin powder to a portion of the device;
- b. aerosolizing the insulin powder to form a cloud of insulin within the device, the cloud comprised of air and suspended insulin particles, the ~~insulin~~ quantity of insulin particles being 2-10 times the dosage of insulin required to be delivered into the patient's blood to achieve acceptable blood glucose level;
- c. administering to the ~~patients~~ patient's blood-stream bloodstream via the ~~patients~~ patient's lungs a sufficient controlled and repeatable quantity of insulin from the cloud to produce an acceptable blood glucose level in the patient.